IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Stanislaw R. Burzynski

Serial No.: 09/863,035

Filed: May 22, 2001

For: TREATMENT REGIMEN FOR ADMINISTRATION OF PHENYLACETYLGLUTAMINE, PHENYLACETYLISOGLUTAMINE, AND/OR PHENYLACETATE

Confirmation No.: 1265

Group Art Unit: 1614

Examiner: COOK, REBECCA

Atty. Dkt. No.: 10379.0047.DVUS01

**DECLARATION OF STANISLAW R. BURZYNSKI, M.D., PH.D.**
**UNDER 37 C.F.R. § 1.132**

I, Stanislaw R. Burzynski, do hereby declare that:

1. I am a citizen of the United States and that my current residential address is 20 West Rivercrest, Houston, Texas, 77042.

2. I received a Medical Doctorate from the Medical Academy in Lublin, Poland, in 1967 and a Doctorate of Philosophy in the field of biochemistry from the Medical Academy of Lublin in 1968. I did my medical internship in internal medicine, surgery, pediatrics, obstetrics, and gynecology from 1969-1970 in pertinent departments at the Lublin Medical Academy. I did my medical residency in the Department of Internal Medicine of the Medical Academy in Lublin from 1969-1970. From 1970-1977 I was a researcher and Assistant Professor at Baylor College of Medicine in Houston, Texas. I am currently the Director and Chairman of the Board of the

Burzynski Research Institute, which I have operated and directed since I founded it in 1977. I am the owner of the Burzynski Clinic, which was founded in 1979.

3. I am completely familiar with the subject matter and disclosure of United States Patent Application Number 09/863,035 (hereafter called "the '035 application"), of which I believe that I am the first and sole inventor. I am generally familiar with the procedures used at the Patent and Trademark Office to consider and distinguish prior art references from pending patent application's claims. I am currently assisting with the prosecution of the '035 application.

4. As Director and Chairman of the Burzynski Research Institute, I am completely familiar with the contents of the paper entitled "*Pharmacokinetics of ANTINEOPLASTON A-10 AND AS2-1 in Patients with Neoplastic Disease*" (hereinafter referred to as "the Waldbillig document"), which was cited by the Examiner as part of the rejection under 35 U.S.C. § 103(a) made in the Office communication dated October 20, 2004.

5. At my direction, the Waldbillig document was written by Robert J. Waldbillig, Ph.D. (hereinafter, Dr. Waldbillig) in his capacity as Vice President of Research at the Burzynski Research Institute, and submitted to the United States Food and Drug Administration (USFDA), as part of an annual report concerning investigational new drug (IND) #43,742.

6. Both in performing the experiments reported in the Waldbillig document and in drafting this document Dr. Waldbillig acted under my instructions and supervision. More particularly, with the purpose of providing further experimental verification of the efficacy of the invention described in U. S. Patent application serial number 09/863,035, I instructed Dr. Waldbillig to perform the tests summarized in the Waldbillig document. Dr. Waldbillig was not involved in the conception of the invention currently claimed in the '035 application. His role has been to

conduct experiments under my instruction, supervision, and control and to draft reports summarizing those experiments.

7. As indicated above, the results of these tests were reported to the USFDA as part of the USFDA-supervised drug approval procedures for the marketing and use of Antineoplastons A10 and AS2-1. Specifically, the Waldbillig document was included as part of an annual report submitted to the USFDA in 1997 for IND #43,742. Included as Appendix A, to provide further evidence of the nature of the Waldbillig document, are copies of the cover letter (dated June 2, 1997) and Form FDA 1571 (also dated June 2, 1997) that were submitted to the USFDA with the 1997 annual report for IND # 43,742.

8. To the best of my knowledge the data that I have submitted to the USFDA as part of drug approval process for IND #43,742, and specifically the Waldbillig document, dated March 14, 1997, are held in confidence by the USFDA and are not publicly available. Therefore, it is my belief that the Waldbillig document is not available as prior art under 35 U.S.C. §§102 or 103.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Dec. 17, 2004

Date

Stanislaw R. Burzynski

# APPENDIX A

BURZYNSKI
RESEARCH INSTITUTE, INC.

June 2, 1997

**FEDERAL EXPRESS and FAX**

Robert J. DeLap, M.D., Ph.D.
Director
Division of Oncology Drug Products
FOOD AND DRUG ADMINISTRATION
1451 Rockville Pike, HFD-150
Rockville, MD 20852

RE: Annual Report 1997
IND# 43,742
Serial# 610

Dear Dr. DeLap:

In response to your letter of February 11, 1997 and in compliance with Section 312.33 of 21CFR, I am providing you with an annual report of the progress of our investigations. The data included in the report are compiled in the items from #1 through #12. Each number of the item corresponds to the number of your request in the letter of February 11, 1997. Unless indicated otherwise, they reflect the status of the IND as of May 15, 1997.

Sincerely,

S. R. Burzynski, M.D., Ph.D.

SRB/sy
cc: Carlton F. Hazlewood, Ph.D.

12000 RICHMOND AVENUE • HOUSTON, TEXAS 77082-2431 • (281) 597-0111 • FAX (281) 597-1166

# DEPARTMENT OF HEALTH AND HUMAN SERVICES
## PUBLIC HEALTH SERVICE
### FOOD AND DRUG ADMINISTRATION
### INVESTIGATIONAL NEW DRUG APPLICATION (IND)
*(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)*

Form Approved: OMB No. 09100-0014.
Expiration Date: March 31, 1998.
*See OMB Statement on Reverse.*

NOTE: No drug may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40).

1. NAME AND ADDRESS OF INVESTIGATOR
STANISLAW R. BURZYNSKI, M.D., Ph.D.

2. DATE OF SUBMISSION
06/02/97

3. ADDRESS *(NUMBER, STREET, CITY, STATE, AND ZIP CODE)*
12000 RICHMOND AVENUE, SUITE 260
HOUSTON, TEXAS 77082-2431

4. TELEPHONE NUMBER *(Include Area Code)*
(281) 597-0111

5. NAME(S) OF DRUG *(Include all available names: Trade, generic, chemical, Code)*
*A10 INJECTIONS*
*AS2-1 INJECTIONS*

6. IND NUMBER *(If previously assigned)*
*#43,742*

7. INDICATION(S) *(Covered by this submission)*

8. PHASE(S) OF CLINICAL INVESTIGATION TO BE CONDUCTED: ☐PHASE 1 ✓PHASE 2 ☐PHASE 3 ☐OTHER_____ *(Specify)*

9. LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIOBIOTIC APPLICATIONS *(21 CFR Part 314)*, DRUG MASTER FILES *(21 CFR 314.420)*, AND PRODUCT LICENSE APPLICATIONS *(21 CFR Part 601)* REFERRED TO IN THIS APPLICATION

IND # 43,742

*IND submissions should be consecutively numbered. The initial IND should be numbered "Serial Number: 000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 001." Subsequent submissions should be numbered consecutively in the order in which they are submitted.*

SERIAL NUMBER: 610

11. THIS SUBMISSION CONTAINS THE FOLLOWING: *(Check all that apply)*

☐ INITIAL INVESTIGATIONAL NEW DRUG APLLICATION (IND)
☐ *RESPONSE TO CLINICAL HOLD*

| *PROTOCOL AMENDMENT(S):* | *INFORMATION AMENDMENT(S):* | *IND SAFETY REPORT(S):* |
|---|---|---|
| ☐ NEW PROTOCOL | ☐ CHEMISTRY/MICROBIOLOGY | ☐ INITIAL WRITTEN REPORT |
| ☐ CHANGE IN PROTOCOL | ☐ PHARMACOLOGY/TOXICOLOGY | ☐ FOLLOW-UP TO A WRITTEN REPORT |
| ☐ NEW INVESTIGATOR | ☐ CLINICAL | |

☐ RESPONSE TO FDA REQUEST FOR INFORMATION ☒ ANNUAL REPORT ☐ GENERAL CORRESPONDENCE

☐ REQUEST FOR REINSTATEMENT OF IND THAT IS WITHDRAWN, INACTIVATED, TERMINATED OR DISCONTINUED ☐ Annual Report 1997 *(Specify)*

CHECK ONLY IF APPLICABLE

JUSTIFICATION STATEMENT MUST BE SUBMITTED WITH APPLICATION FOR ANY CHECKED BELOW. REFER TO 21 CFR 312.23 FOR FURTHER INFORMATION.

☐ TREATMENT IND 21 CFR 312.34 ☐ TREATMENT PROTOCOL 21 CFR 312.35 ☐ SUBPART E REQUEST 21 CFR 312.36

FOR FDA USE ONLY

| CDR/DGD RECEIPT STAMP | DDR RECEIPT STAMP | IND NUMBER ASSIGNED |
|---|---|---|
| | | DIVISION ASSIGNMENT: |

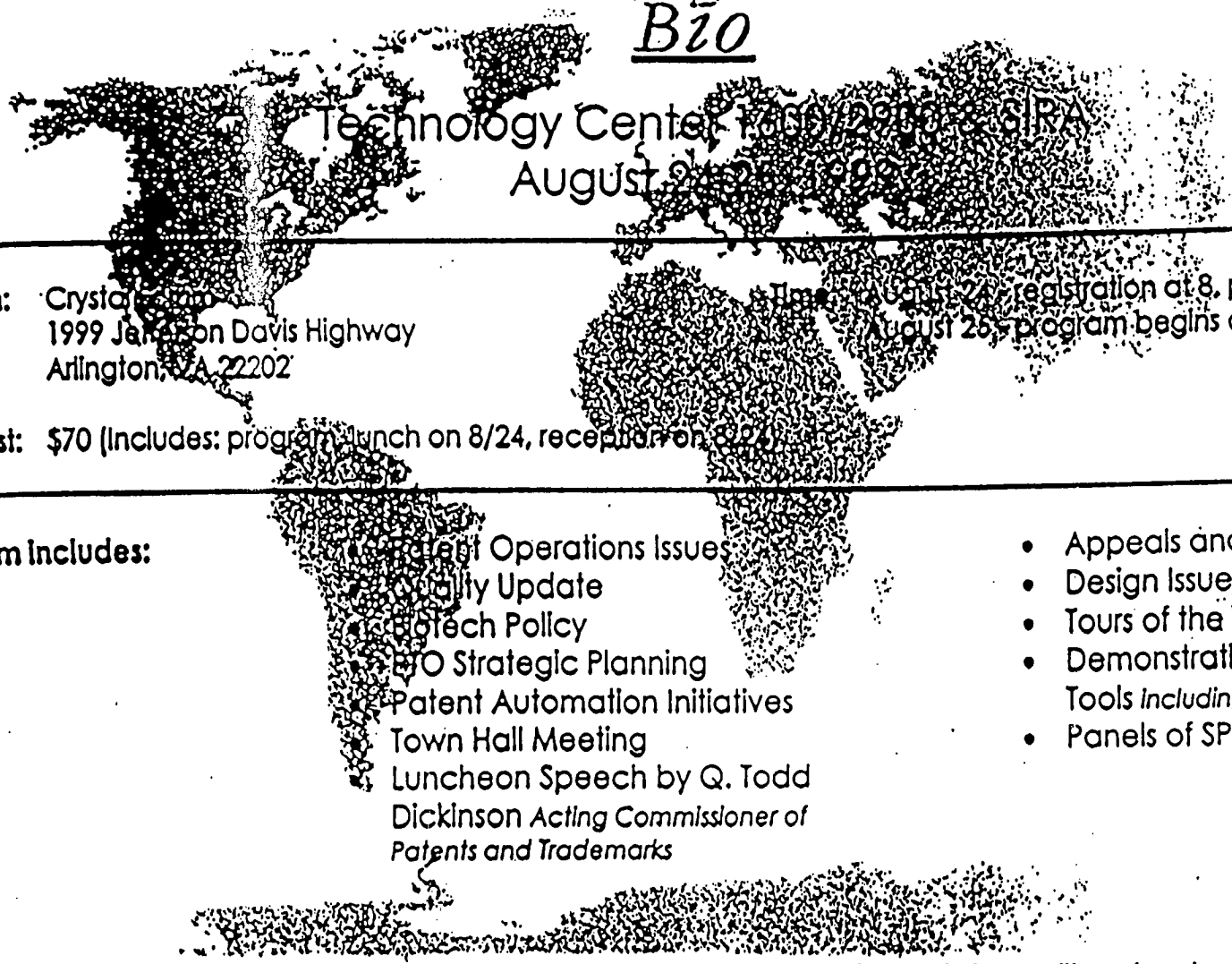
FORM FDA 1571 (10/89) PREVIOUS EDITION IS OBSOLETE

# OPEN HOUSE PROGRAM

## BIO

## Technology Center 1700/2900 & SIRA

## August 24-25, 1999



**Location:** Crystal Plaza
1999 Jefferson Davis Highway
Arlington, VA 22202

**Time:** August 24 - registration at 8, program begins at 8:30
August 25 - program begins at 8

**Cost:** $70 (includes: program, lunch on 8/24, reception on 8/24)

**Program Includes:**

- Patent Operations Issues
- Quality Update
- Biotech Policy
- PTO Strategic Planning
- Patent Automation Initiatives
- Town Hall Meeting
- Luncheon Speech by Q. Todd Dickinson *Acting Commissioner of Patents and Trademarks*
- Appeals and Interferences
- Design Issues
- Tours of the Technology Center
- Demonstrations of Automation Tools *including Patentin*
- Panels of SPEs on current topics

**For more information or to register by phone, call 703-308-1234; your payment can be made by credit card or check made payable to "BIO"**